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EXAMINER	
SCHLIENTZ, LEAH H	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/679,052	**Applicant(s)** WILLIAMS, ARCHIE B.	
	Examiner Leah Schlientz	**Art Unit** 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-85 is/are pending in the application.
4a) Of the above claim(s) 13,14,28,46,47 and 49-61 is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) 1-12,15-27,29-45,48 and 62-70 is/are rejected.
7)☐ Claim(s) 71-85 is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on 03 October 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/03/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species: a gadolinium-based contrast agent, which is classified in class 424, subclass 9.36, an iodide-containing contrast agent, which is classified in class 424, subclass 9.4 and a barium-containing contrast agent, which is classified in class 424, subclass 9.41. The species are distinct because of their materially different design, function, and effect. The different compositions of the contrast agents are central to their function. For example, barium and iodide-containing compounds traditionally function by altering x-rays, such as for use in CT and other imaging techniques, while the gadolinium-containing and other paramagnetic transition metal-based compounds traditionally function by altering magnetic response, such as for use in MRI imaging techniques. Thus, by the materially different design, function, and effect of the respective species, these related species are distinct.

This application contains claims directed to the following patentably distinct species: methods of imaging of an anatomic segment of an individual, wherein the gastrointestinal tract, small intestine, colon, pancreas, duodenum, cecum, bowel, large intestine, jejunum, ileum, appendix, pancreas, sigmoid, rectum, or stomach are imaged. The various anatomic segments are distinct because of their different structures and biological functions.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Mr. Parker on June 30, 2006 a provisional election was made with traverse to prosecute the invention of a barium-containing contrast agent, claim 11, and the method of imaging of an anatomic segment of an individual, wherein the colon is imaged, claim 48. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13, 14, 28, 46, 47, and 49 –

61 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 34 – 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims as written are ambiguous because it is unclear what diagnostic procedure Applicant is referring to. Please clarify in order that one may readily ascertain what is being claimed. For example, the action stated in step (b) does not clarify the medical or diagnostic procedure that is performed.

4. Claims 27, 29, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 refers to a contrast media comprising less than 2 w/v% of a barium-based compound, about 0.05% to about 15% of a stabilizing agent, and about 1% to about 25% of an osmotic agent. Claim 27, which is dependent upon claim 23, is indefinite because it does not constitute a further limitation over claim 23, rather it increases the range of the stabilizing agent to about 0.01% to about 30%. Claim 29, which is dependent upon claim 23, is indefinite because it does not constitute a further limitation over claim 23, rather it increases the

range of the osmotic agent to about 0.05% to about 60%. Claim 33, which is dependent upon claim 23, is indefinite because it does not constitute a further limitation over claim 23, rather it increases the range of the barium-based compound to less than 5%.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramm *et al.* (Phys. Med. Biol., 2001, 46, p. 2631-2635).

Ramm *et al.* teach that Hounsfield values (HU) are dependent upon the concentration of barium sulfate in a computed tomography (CT) contrast agent and that HUs increase with increasing $BaSO_4$ concentration (page 2632). The Hounsfield value, as defined in paragraph 32 of the specification, is the unit of x-ray attenuation used for CT scans. Ramm prepared a 10 mg/cm^3 (or 1% w/v) barium-sulfate containing contrast agent that clearly shows a measured HU value of less than 200 (see page 2632 and graph on page 2633). Claims 1 refers to a contrast media having a Hounsfield value from about -500 to about 250, claim 2 narrows the range of the Hounsfield value to between about 1 and about 200. The Hounsfield value is an inherent property of the contrast agent, and thus any barium sulfate-containing contrast agent of suitable concentration would have a Hounsfield value in the stated range.

7. Claims 1, 6, 11, 12, 15, 16, 20 – 22, 34, 40, 45, 48, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Nyman *et al. (Acta Radiol. Diagn.*, 1984, 25, p. 121-124).

Nyman discloses a barium sulfate-containing contrast medium, E-Z-CAT, for use in CT of the abdomen. Regarding claim 1, the contrast medium evidenced by Nyman has a Hounsfield value of 246 (page 121). Regarding claims 6, 11, and 12, the contrast medium has a concentration of 1.7% barium sulfate by weight. Regarding claim 15, E-Z-CAT comprises vegetable gum (page 121), which is known by those familiar in the art to modify the viscosity of a substance, and thus would act as a stabilizing agent. Regarding claims 16, 20, 21, and 22, E-Z-CAT further comprises sorbitol (page 121), which is a sugar-based compound, and is more specifically a polysaccharide, and which is known by those familiar in the art to act an osmotic agent. Regarding claims 34 and 40, a diagnostic procedure is performed after orally administering E-Z-CAT to an individual, wherein the medical or diagnostic procedure is a CT examination (page 121). With regard to claims 45 and 48, the gastrointestinal tract, including the colon, was imaged after oral administration of E-Z-CAT (page 122). Regarding claim 70, several sections of the gastrointestinal tract, such as the stomach and intestines, for example, were distended or filled with said contrast media for imaging (page 122).

8. Claims 1 – 7, 11, 12, 34 – 41, 45, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson *et al.* (U. S. 6,477,401 B1 issued 11/5/2002).

Johnson *et al.* teach a barium sulfate suspension from 0.8% to 1.5% barium used in a method for generating colonography images of a patient (see claims 8 and 9). Regarding claims 1 – 5 and 34 – 39, Johnson *et al.* do not disclose a Hounsfield value, but the Hounsfield value is an inherent property of the contrast agent, and thus a barium sulfate-containing contrast agent of suitable concentration could be expected to have a Hounsfield value in the stated range. The medical or diagnostic procedure taught by Johnson is colorectal screening (i.e. screening the color for cancer). Regarding claims 6 – 7 and 40 – 41, the concentration of barium sulfate was between 0.8% and 1.5% (claim 9). Regarding claims 45 and 48, the colon was imaged upon administration of said contrast agent (claims 8 and 9).

9. Claims 1, 6, 11, 12, 34, 40, 45, 62 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Zeman *et al.* (*Am. J. Roentgenology*, 1998, 170, p. 1427 – 1438).

Zemen *et al.* teach the use of helical CT surveys for performing various routine clinical examinations, including the examination of the abdomen (page 1429). Regarding claims 1, 6, 11, and 12, Zemen states that for elective survey CT examinations, patients ingest 900 ml of 1.5% barium sulfate oral contrast agent (page

1429). Zemen *et al.* do not disclose a Hounsfield value, but the Hounsfield value is an inherent property of the contrast agent, and the stated barium sulfate-containing contrast agent is of suitable concentration to be expected to have a Hounsfield value in the claimed range. Regarding claims 34, 40, and 45, the method of imaging is helical CT. Regarding claims 62 and 66, pancreatitis is a disease of the pancreas.

10. Claims 1, 6, 11, 12, 34, 40, 45, 62, 63, 65, 67, 69, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Gore *et al.* (*Am. J. Roentgenology*, 1984, 143, p. 279 – 284).

Gore *et al.* teach the use of CT for differentiating between patients with Crohn's disease and ulcerative colitis (abstract). Regarding claims 1, 6, 11, and 12, the contrast agent used by Gore *et al.* is E-Z-CAT dilute barium sulfate suspension (page 280), which is known to have a 1.7% w/v barium concentration. Gore *et al.* do not disclose a Hounsfield value, but the Hounsfield value is an inherent property of the contrast agent, and the contrast agent is of suitable concentration to be expected to have a Hounsfield value in the claimed range. With respect to claims 34, 40, and 45, and 48, the method of imaging is CT examination, and the colon is imaged. Regarding claims 62, 63, and 65, the presence of active ulcers, ulcerative colitis, Crohn's disease, and/or enlarged lymph nodes were diagnosed (pages 280 – 281). Regarding claim 69, narrowing of the lumen of the colon was observed (page 279 and 281). Regarding claim 70, the colon was distended for CT imaging (page 280).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1 – 12, 15 – 27, 29 – 45, 69, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Widder (US 5,611,342 issued 3/18/1997) in view of Fuisz *et al.* (US 6,337,082 issued 1/8/2002) in further view of Nyman *(Acta Radiol. Diagn.*, 1984, 25, p. 121-124).

Widder discloses a method of CT imaging of the upper gastrointestinal tract using a low-density CT contrast agent. The difficulties associated with positive contrast agents or the absence of a contrast agent can be overcome by introduction of a low density contrast agent into the gastrointestinal tract (column 2, lines 15 – 19). The term “low-density” contrast agent is defined as a contrast media with a low or negative HU (i.e. less than about 100 HU, preferably less than 10 HU, and most preferably less than 0 HU (column 2, lines 32 – 42)). The contrast agent taught by Widder comprises a biocompatible material that increases osmolality and/or the viscosity (column 4, lines 33 – 37 and claim 9). Thus, the biocompatible material of Widder addresses Applicant's claims to a contrast agent comprising an osmotic agent and/or a stabilizing agent (defined by Applicant as a substance that modifies the viscosity of a substance). Suitable substances are further defined by Widder to include 10% to 50% of a polysaccharide, such as sorbose, as an osmotic agent (column 4, lines 48 – 63), and/or 0.5% to 0.8% of a hydrocolloid, such as xanthan gum, as viscosity modifier (column 4, lines 64 – 66 continuing to column 5, lines 1 – 25). The ranges of Hounsfield values and concentrations of osmotic agents and stabilizing agents in the contrast medium recited by Widder address all of the concentration ranges claimed by Applicant.

Widder fails to recite a barium-containing contrast agent, and cites the polysaccharide sorbose, rather than sorbitol as claimed.

Fuisz *et al.* disclose an x-ray contrast medium comprising barium sulfate, a gelling agent, such as xanthan gum, from 3% to 50%, and a sugar, such as sorbitol, from 10% to 20% (claims 1, 6 – 13, and 16 – 18).

Fuisz *et al.* fail to recite a barium concentration.

Nyman *et al.* teach a relatively low-density contrast agent, E-Z-CAT, which comprises sorbitol (an osmotic agent), vegetable gum (a stabilizing agent), and 1.7% barium sulfate for use in distending and imaging the gastrointestinal tract (page 121).

Nyman fails to recite a specific concentration of osmotic agent or stabilizing agent.

It would have been obvious to one of ordinary skill in the art to combine the low density contrast media for imaging the gastrointestinal tract comprising the claimed specific osmotic agent (sorbitol) and stabilizing agent (xanthan gum) in the range of concentrations taught by Widder with the barium sulfate-containing contrast media also comprising sorbitol and xanthan gum taught by Fuisz. The motivation to prepare such a contrast agent been demonstrated by Widder, who teaches the benefits of using a low density contrast media, such as enhanced CT imaging of the tissues and organs of the upper gastrointestinal tract wherein the upper gastrointestinal tract is filled with a low density contrast agent. Said contrast agent comprising osmotic and/or viscosity modifiers has a prolonged gastric emptying time, thus causing the lumen of the upper gastrointestinal tract to appear less dense than the gastrointestinal tract walls and upper abdominal organ (see abstract). Furthermore, because the Hounsfield value is an inherent property of the contrast agent, and is directly dependent upon the concentration of barium sulfate, it would have been obvious to include a slightly lower percentage of barium sulfate than that of Nyman to achieve a low density contrast media, such as less than 100 HU, preferably less than 10 HU, or more preferably less than 0 HU as defined by Widder.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ

233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.) see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")

13. Claims 1 – 6, 11, 12, 15 – 21, 34 – 45, 48, 62 – 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Widder (US 5,611,342 issued 3/18/1997) in view of Balthazar *et al.* (*Am. J. Roentgenology*, 1988, 150, p. 301 – 306).

Widder discloses a method of CT imaging of the upper gastrointestinal tract using a low-density CT contrast agent, wherein said contrast agent has the same range of Hounsfield values and concentrations of osmotic agents and/or stabilizing agents as the contrast media claimed by Applicant.

Widder fails to recite a barium-containing contrast agent, and cites the polysaccharide sorbose, rather than sorbitol as claimed. Widder also fails to recite a method of detecting colon cancer upon administration of a contrast agent.

Balthazar *et al.* disclose the use of CT imaging for evaluation of patients with colonic carcinoma and detection of colonic tumors in patients with nonspecific abdominal complaints. A 2.0% barium sulfate-containing contrast agent was used in these studies (abstract and page 302). The sensitivity of CT detection was dependent upon the size of the lesion and the quality of the CT examination (page 304).

Balthazar *et al.* fail to recite a contrast agent comprising a stabilizing agent and an osmotic agent, and do not disclose a Hounsfield value of the contrast media.

It would have been obvious to one of ordinary skill in the art to combine the low density contrast media for imaging the gastrointestinal tract comprising an osmotic agent and stabilizing agent (xanthan gum) in the range of concentrations taught by Widder with the relatively low density barium sulfate-containing contrast media taught by Balthazar *et al.* The motivation to prepare such a contrast agent has been demonstrated by Balthazar, who teaches the benefit of using a relatively low-density barium sulfate-containing contrast media for the evaluation of patients with colonic carcinoma, as well as for the detection of colonic tumors.

14. Claims 1 – 6, 11, 12, 15 – 21, 34 – 45, 48, 62, 63, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Widder (US 5,611,342 issued 3/18/1997) in view of Ha *et al.* (*Radiology*, 1998, 209, p. 449 – 454).

Widder discloses a method of CT imaging of the upper gastrointestinal tract using a low-density CT contrast agent, wherein said contrast agent has the same range of Hounsfield values and concentrations of osmotic agents and stabilizing agents as the contrast media claimed by Applicant.

Widder fails to recite a barium-containing contrast agent, and cites the polysaccharide sorbose, rather than sorbitol as claimed. Widder also fails to recite a method of diagnosing a disease of the vascular system upon administration of a contrast agent.

Ha *et al.* disclose the use of CT imaging for the evaluation of patients with Behçet syndrome, which is considered to be a disease related to the vascular system (page 450). Ha *et al.* teach that CT has a primary role in detection of the lesions associated with the disease in patients with Behçet syndrome, as well as to differentiate between Behçet syndrome and other diseases that produce similar gastrointestinal symptoms (page 452 – 453). A 2% barium sulfate-containing contrast agent was used in these studies.

Ha *et al.* fail to recite a contrast agent comprising a stabilizing agent and an osmotic agent, and do not disclose a Hounsfield value of the contrast media.

It would have been obvious to one of ordinary skill in the art to combine the low density contrast media for imaging the gastrointestinal tract comprising an osmotic agent and stabilizing agent (xanthan gum) in the range of concentrations taught by Widder with the relatively low density barium sulfate-containing contrast media taught by Ha *et al.* The motivation to use such a contrast agent has been demonstrated by Ha *et al.*, who teach the benefit of using a relatively low-density barium sulfate-containing contrast media for diagnosis of the presence of lesions in the evaluation of patients with Behçet syndrome.

Claim Objections

15. Claims 71 – 85 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Information Disclosure Statement

16. The information disclosure statement filed 10/03/2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The document referenced as Department of Health and Human Services – Ltr to Madhu Anant dated 3-31-99, re: NDA 20-773 – SonoRx (simethicone 7.5) mg/ml.) was omitted.

Conclusion

17. No claims are allowed at this time.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday between 8 AM - 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lhs

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER